UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

IN RE: TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LITIGATION	**CASE NO. 1:14-CV-01748** **MDL 2545** **JUDGE MATTHEW F. KENNELLY**

BESINS HEALTHCARE INC.'S AND BESINS HEALTHCARE, S.A.'S REPLY IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT

Plaintiffs' Response in Opposition to Besins' Motion for Summary Judgment ("Opposition") relies on self-serving, bare allegations from the Complaint and generalized, uncontroversial facts about the Besins/AbbVie relationship. But Plaintiffs have not identified ***any*** specific tortious conduct of either Besins S.A. or Besins Inc., let alone an iota of supporting evidence. As a result, Plaintiffs' claims as to these Besins Defendants—no matter how labeled—fail as a matter of law.

It is undisputed that Besins S.A. has never marketed AndroGel in the United States and Besins Inc. has never manufactured, sold, distributed, or promoted AndroGel. Plaintiffs now turn their focus to Besins S.A.'s pharmacovigilance database, and Besins Inc.'s co-ownership of the AndroGel patent, but these basic and uncontroverted facts do not support a finding that any tortious conduct by movants occurred. Plaintiffs have not made a sufficient showing to keep Besins in these cases, and summary judgment is required.

LOCAL RULE 56.1 STATEMENT OF MATERIAL FACTS IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

Pursuant to Rule 56(c) of the Federal Rules of Civil Procedure and Rule 56.1 of the Local Civil Rules of the United States District Court for the Northern District of Illinois, Besins respectfully submits these objections to Plaintiffs' Response to Besins' Statement of Facts and

reply to Plaintiffs' Statement of Material Facts in connection with their Motion for Summary Judgment ("Motion"). For the Court's convenience, Besins includes, in Section I, their original statements of undisputed facts together with Plaintiffs' responses and AbbVie's objections pursuant to Rule 56(c). In Section II, Besins includes Plaintiffs' Statement of Material Facts and Besins' replies pursuant to Local Rule 56.1.

I. BESINS' RULE 56(C) OBJECTIONS TO PLAINTIFFS' RESPONSE TO BESINS' STATEMENT OF FACTS

THE PARTIES

1. Plaintiffs are individuals who reside and are citizens of various states in the United States, and who allegedly experienced personal injuries from allegedly using the prescription drug AndroGel. Fourth Am. Master Long-Form Compl. (the "Complaint") ¶¶ 4, 6, 14, MDL ECF No. 1345.

RESPONSE TO PARAGRAPH 1: Admit.

OBJECTIONS TO RESPONSE TO PARAGRAPH 1: None.

2. Defendant Besins Healthcare, S.A. is a privately-held Belgian corporation with its headquarters in Monaco. Master Answer of Besins S.A. ¶ 25, MDL ECF No. 1589.

RESPONSE TO PARAGRAPH 2: Admit.

OBJECTIONS TO RESPONSE TO PARAGRAPH 2: None.

3. Defendant Besins Healthcare, Inc. is a Delaware corporation with its principal place of business in Virginia and is a wholly owned subsidiary of Besins S.A. Master Answer of Besins Inc. ¶ 25, MDL ECF No. 1037.

RESPONSE TO PARAGRAPH 3: Admit.

OBJECTIONS TO RESPONSE TO PARAGRAPH 3: None.

VENUE AND JURISDICTION

4. Defendants AbbVie Inc. and Abbott Laboratories are located in Lake County, Illinois, which is within the judicial boundaries of the Northern District of Illinois. *See* Master Answer of AbbVie Inc., Abbott Labs., AbbVie Prods. LLC and Unimed Pharms., LLC ¶¶ 17-18, MDL ECF No. 755. Venue is proper under 28 U.S.C. § 1391.

RESPONSE TO PARAGRAPH 4: Admit.

OBJECTIONS TO RESPONSE TO PARAGRAPH 4: None.

5. Plaintiffs seek damages in excess of $75,000. Compl. ¶ 13. This Court has subject matter jurisdiction under 28 U.S.C. § 1332 as to the claims of the respective Plaintiffs.

RESPONSE TO PARAGRAPH 5: Admit.

OBJECTIONS TO RESPONSE TO PARAGRAPH 5: None.

STATEMENT OF FACTS

6. Besins S.A. has never marketed AndroGel in the United States. MacAllister Dep. 55:9-15; 208:14-24, Ex. A.

RESPONSE TO PARAGRAPH 6: Admit.

OBJECTIONS TO RESPONSE TO PARAGRAPH 6: None.

7. Besins S.A. has no responsibility over AbbVie's marketing activities. *Id.* 147:24-150:4.

RESPONSE TO PARAGRAPH 7: Disputed, given the fact that the Besins defendants attended several in-person meetings and telephone conferences and sat on joint steering committees with AbbVie, during which time AndroGel marketing activities were discussed. Ex. 1, Besins 30(b)(6) Tr. at 28:1-29:24; 34:10-54:13; 59:17-64:4; 83:3-10.

OBJECTIONS TO RESPONSE TO PARAGRAPH 7: Besins' statement is not genuinely disputed. Plaintiffs' response does not dispute that Besins had no *responsibility* over AbbVie's marketing activities. In addition, the cited deposition excerpts note that Besins' meetings with AbbVie were "very sparse" and that Besins' marketing and sales divisions were never represented at these meetings.

8. Besins Inc. has never manufactured, sold, distributed, or promoted AndroGel. *See* Master Answer of Besins Inc. ¶ 4, MDL ECF No. 1037.

RESPONSE TO PARAGRAPH 8: Admit.

OBJECTIONS TO RESPONSE TO PARAGRAPH 8: None.

9. Besins Inc. is not a party to either the Supply Agreement or License Agreement that govern the relationship between Besins S.A. and AbbVie Inc. regarding the manufacture and distribution of AndroGel in the United States. *See* Resp. of Besins Healthcare Inc. to Pls.' Interrogs. at 18-19, Ex. B.

RESPONSE TO PARAGRAPH 9: Admit.

OBJECTIONS TO RESPONSE TO PARAGRAPH 9: None.

10. Further, Besins Inc. has no involvement in the study, testing, manufacture, sales, marketing, or distribution of AndroGel. *See id*. at 22.

RESPONSE TO PARAGRAPH 10: Disputed. Besins Inc. was primarily "responsible for the relationship with AbbVie in the United States," which included joint AndroGel steering committees and boards. Ex. 2, MacAllister Tr. at 28:1-31:1; 56:8-16. "All aspects of the product," such as patent, supply, sales, and marketing issues, were presented and discussed. *Id*. at 29:12-24.

OBJECTIONS TO RESPONSE TO PARAGRAPH 10: Besins' statement is not genuinely disputed. A complete reading of the cited deposition transcript reveals that Besins Inc. was primarily responsible for the relationship with AbbVie in the U.S. regarding issues such as "contractual issues [and] patent issues." MacAllister Dep. 56:2-20, Pl. Ex. 2. Plaintiffs' response does not dispute that Besins Inc. had no involvement in other aspects, such as marketing or distribution. When Mr. MacAllister discussed the "irregular" meetings that occurred between Besins and AbbVie to discuss "all aspects of the product," he explicitly clarified that "all aspects" meant only that "[p]atent issues [and] supply issues" relating to AndroGel were discussed. *Id.* 29:7-14.

II. BESINS' RULE 56.1 REPLY TO PLAINTIFFS' STATEMENT OF MATERIAL FACTS

11. Besins S.A. co-developed the pharmaceutical formulation for AndroGel. Ex. 3, Master Answer of Defendant Besins Healthcare, S.A., ¶ 55-56, Master Dkt. No. 1589.

REPLY TO PARAGRAPH 11: Uncontroverted.

12. Besins S.A. employs staff with responsibility related to the clinical development of AndroGel, staff who are responsible for reporting, investigating, and analyzing spontaneous adverse reactions and/or complaints of side effects related to AndroGel, and staff who are responsible for medical knowledge and/or supervisory medical oversight concerning AndroGel. *See* Ex. 4, Response of Besins Healthcare, S.A. to Plaintiffs' Interrogatories, dated December 12, 2016, ("Besins S.A. Dec. 12, 2016 Interrogatory Responses") at 9.

REPLY TO PARAGRAPH 12: Uncontroverted.

13. Besins S.A. maintains the worldwide safety database, or "pharmacovigilance file," for AndroGel, which includes all reported adverse events for AndroGel from within the United States and from outside the United States. Ex. 1 at 73:8- 18.

REPLY TO PARAGRAPH 13: Uncontroverted.

14. Besins S.A.'s Pharmacovigilance Department is responsible for the following tasks with respect to AndroGel:

- Collection of all safety information on a product obtained from the published literature, spontaneous case reports or clinical studies;
- Ensure timely expedited reporting of adverse events to the Competent Authorities;
- Continuously evaluate the risk/benefit ratio through signal detection activities;
- Production of Periodic Safety Update Reports (PSURs) for Besins Healthcare products and timely submission to the Competent Authorities;
- Update Risk Management Plans (RMPs) and Company Core Safety Information (CCSI);
- Production and update Safety Data Exchange Agreements (SDEAs) between Besins Healthcare and our partners;

- Answer safety reports received from Licensing Partners, Competent Authorities, other Besins Healthcare Departments, consumer or Healthcare professionals.

Ex. 5 at Besins 000087-000100.

REPLY TO PARAGRAPH 14: Uncontroverted.

15. Besins S.A.'s Global Safety Committee is responsible for the following tasks with respect to AndroGel:

- Analyzing signals highlighted during signal detection;
- Assessing the risk/benefit ratio of Besins Healthcare products;
- Reviewing of Company Core Safety Information (CCSI) and Risk Management Plans (RMPs).

Id.

REPLY TO PARAGRAPH 15: Uncontroverted.

16. Besins S.A.'s Global Safety Committee is responsible for signal detection, meaning Besins S.A. assesses whether there are new safety signals associated with Besins' products, including AndroGel. Ex. 6 at Besins 000176.

REPLY TO PARAGRAPH 16: Uncontroverted.

17. Besins S.A.'s Global Safety Committee is further responsible for determining whether any course of action, such as suspending marketing authorization of a Besins product if required and if so to escalate that to the Global Labeling Committee. Ex. 6 at Besins 000178.

REPLY TO PARAGRAPH 17: Uncontroverted.

18. Besins S.A. and AbbVie entered a Safety Data Exchange Agreement dated January 28, 2013, which was a "reciprocal agreement where adverse events are exchanged between Abbvie and Besins and between Besins and AbbVie." Ex. 7; Ex. 1 at 71:5-14.

REPLY TO PARAGRAPH 18: Controverted. The Safety Data Exchange Agreement is dated February 11, 2013.

19. The Safety Data Exchange Agreement was entered "for purposes of facilitating accurate, timely exchange of adverse events and each company's compliance with regulatory reporting requirements in each company's territories." Ex. 7 at I.

REPLY TO PARAGRAPH 19: Uncontroverted.

20. Prior to the Safety Data Exchange Agreement dated January 28, 2013, Besins and AbbVie's predecessors had Pharmacovigilance Agreements dated July 30, 2003, and amended November 8, 2004 and May 22, 2006. Ex. 8 – 10.

REPLY TO PARAGRAPH 20: Controverted. The Safety Data Exchange Agreement is dated February 11, 2013.

21. Pursuant to the Safety Data Exchange Agreement, Besins S.A. agreed to: "be responsible for detection and evaluation of safety signals" and to "communicate any identified safety signal upon confirmation of the validity of the safety signal." Ex. 7 at XII, p. 9.

REPLY TO PARAGRAPH 21: Controverted. Pursuant to the Safety Data Exchange Agreement, both AbbVie and Besins S.A. agreed to "be responsible for detection and evaluation of safety signals" and to "communicate any identified safety signal upon confirmation of the validity of the safety signal."

22. Besins Healthcare is a "TRT Sponsor" that contributed to the "industry briefing book" submitted to the FDA by TRT sponsors in advance of the September 2014 Advisory Committee meeting, which addressed, *inter alia*, the scope of the approved indication for AndroGel, guidelines for prescription of AndroGel, risks associated with testosterone replacement therapy, purported benefits testosterone replacement therapy, and estimated prevalence of hypogonadism. Ex. 11 at 16.

REPLY TO PARAGRAPH 22: Controverted. Besins did not make any contribution to the FDA Advisory Committee meeting. Bua Dep. 68:5-11, Pl. Ex. 1. However, uncontroverted that Besins Healthcare is listed as a "TRT Sponsor" to the "industry briefing book" submitted to the FDA by TRT sponsors in advance of the September 2014 Advisory Committee meeting, which addressed, *inter alia*, the scope of the approved

indication for TRT, guidelines for prescription of TRT, risks associated with TRT, purported benefits of TRT, and estimated prevalence of hypogonadism.[1]

23. The Besins defendants participated in the Advisory Committee convened by the U.S. Food and Drug Administration in September 2014 and hosted at least one event in Herndon, Virginia, that was attended by U.S. testosterone experts known as key opinion leaders ("KOLs") in connection with the FDA Advisory Committee meeting in September 2014. Ex. 12; Ex. 1 at 68:1-14.

REPLY TO PARAGRAPH 23: Uncontroverted.

24. Besins employees Paul Piette and Jean-Paul Dutret, "medical liaisons" employed by Besins, were in attendance at the FDA Advisory Committee meeting. Ex. 1, Bua Tr. 67:21-69:15. Mr. Piette was "responsible for medical affairs worldwide ex-U.S." and Mr. Dutret was responsible for "worldwide global ex-U.S. pharmacovigilance." Ex. 1 at 69: 6-15. Jay Bua, President of Besins Inc., who also sits on the Board of Directors for Besins S.A. attended the KOL meeting. *Id*. at 68:21-69:5.

REPLY TO PARAGRAPH 24: Controverted. Besins did not make any contribution to the FDA Advisory Committee meeting. Bua Dep. 68:5-11, Pl. Ex. 1. Besins employees Paul Piette and Jean-Paul Dutret, "medical liaisons" employed by Besins, were in attendance at the Herndon, Virginia KOL meeting event, not the FDA Advisory Committee meeting. *Id.* 68:5-69:15. Both of these "medical liaisons" had responsibilities outside of the United States: Mr. Piette was "responsible for medical affairs worldwide ex-US" and Mr. Dutret "was worldwide global ex-US pharmacovigilance." *Id.* 69:8-15. Mr. Bua only attended "part of the meeting." *Id*. 69:1-2.

[1] Because Besins is AbbVie's manufacturer and licensor, AbbVie agreed to have Besins participate in the Advisory Committee meeting to be kept abreast of developments occurring in the United States, which could have implications for Besins' role outside of the United States; as a result, Besins was listed as a "TRT Sponsor," but did not contribute to the Advisory Committee meeting. *See* Bua Dep. 68:5-11, Pl. Ex. 1.

25. The Besins defendants had several annual meetings with AbbVie regarding sales of AndroGel in the United States. Ex. 1, Besins 30(b)(6) Tr. at 28:1-29:24; 34:10-54:13; 59:17-64:4; 83:3-10.

REPLY TO PARAGRAPH 25: Controverted. The cited deposition excerpts note that Besins' meetings with AbbVie were "very sparse."

26. The Besins defendants have received millions of dollars annually from sales of AndroGel from within the United States. Besins' royalties from U.S. AndroGel sales were:

- 2000 (Q4): $603,572
- 2001: $7,815,433
- 2002: $14,633,736
- 2003: $22,384,257
- 2004: $22,922,921
- 2005: $22,609,778
- 2006: $26,215,019
- 2007: $32,250,824
- 2008: $37,713,200
- 2009: $48,297,504
- 2010: $58,038,192
- 2011: $68,444,275
- 2012: $90,361,595
- 2013, $80,061,327
- 2014: $72,791,626
- 2015: $28,667,865

Ex. 13; Ex. 1 at 18:14-21:11; and Ex. 2 at 183:8-188:8.

REPLY TO PARAGRAPH 26: Controverted. Documents cited do not provide royalty information prior to 2010. Besins' royalties from U.S. AndroGel sales in 2014 was $72,791,526. Bua Dep. 20:10-12, Pl. Ex. 1.

27. AndroGel royalties in the United States have accounted for approximately one-third of Besins' revenues. Ex. 1, Besins 30(b)(6) Tr. at 23:14-26:10.

REPLY TO PARAGRAPH 27: Controverted. 28-30% percent, or less than one-third, of Besins' revenues were generated from AndroGel royalties in the United States. Bua Dep. 23:14-26:10, Pl. Ex. 1.

28. The Besins defendants knew there was insufficient evidence regarding cardiovascular risks associated with AndroGel, but that they should not pursue safety studies and, instead, continue profiting off of AndroGel sales. Ex. 14.

REPLY TO PARAGRAPH 28: Controverted. Besins Inc. never manufactured, sold, distributed, or promoted AndroGel. SOF ¶ 8. The evidence regarding potential cardiovascular risks associated with AndroGel also was insufficient to require any action by Besins S.A. MacAllister Dep. 156:10-21; 157:17-158:4; 158:23-159:4, Pl. Ex. 2. Besins considered the studies that had been done showing potential cardiovascular risks to be unreliable, but did not have a large, good study with which to counter the unreliable studies. *Id*. There is still no substantial evidence of cardiovascular risk associated with AndroGel. *Id.* 161:23-162:1. In addition, under the terms of the relationship between Besins S.A. and AbbVie, Besins S.A. had no responsibility or even any right to provide qualitative assessment of any adverse events, and no responsibility or right to initiate or supervise any additional safety studies. *Id.* 154:19-22; 155:10-14; 163:5-9. Furthermore, AndroGel was licensed to AbbVie when it was still in formulation. *Id*. 163:13-14.

ARGUMENT

All of Plaintiffs' surviving claims against Besins Defendants boil down to the same set of allegations—that Besins' relationship with AbbVie resulted in particular pharmacovigilance and reporting obligations for AndroGel. Plaintiffs' accusations are conclusory and unsupported by specific facts in the record. As a result, summary judgment is appropriate for the claims against Besins, whether styled as strict liability, negligence, redhibition, or unjust enrichment.

On the strict liability claim, Plaintiffs argue that Besins has not made any new arguments since their Motion to Dismiss, which the Court previously denied. Opp'n at 4-5. But Plaintiffs' "[r]eliance on [the] court's decision on a motion to dismiss is inappropriate at the summary judgment stage. Different standards apply to a Rule 12(b)(6) motion to dismiss and a Rule 56(c) motion for summary judgment." *Bergt v. McDougal Littell*, 661 F. Supp. 2d 916, 923 (N.D. Ill. 2009). Plaintiffs "must go beyond mere allegations and offer specific facts showing that there is a genuine issue for trial." *Jaske v. Zimmer, Inc.*, No. 03 C 2939, 2010 WL 345897, at *5 (N.D. Ill. Jan. 26, 2010) (citations omitted). Plaintiffs here have failed to do so. The Complaint's vague and

generalized allegations about the alleged risks of AndroGel are "[c]onclusory allegations, unsupported by specific facts" that should be dismissed at the summary judgment stage. *Id.* There simply is no evidence that AndroGel's physical design was defective.

Plaintiffs also argue that their redhibition claim should survive because it is "more akin to its design defect claim." Opp'n at 5. This is wrong as a matter of Louisiana law; redhibition is more like a breach of implied warranty, *see* Mot. at 9, and thus should be dismissed for the same reason this Court previously dismissed warranty claims against Besins. Even if considered akin to a design defect claim, however, Plaintiffs' redhibition claims fail for the same reason as the design defect claims. *See* Mot. at 6-8.

Plaintiffs' negligence claim centers on Besins S.A.'s maintenance of the global pharmacovigilance database and supposed failures in adequately reporting risk information. Opp'n at 6-8. Those claims fail because Besins S.A.'s maintenance of the pharmacovigilance database is only for use ***outside*** of the United States. Bua Dep. 103:23-104:22, Pl. Ex. 1. The undisputed record establishes that ***AbbVie*** has sole responsibility for reporting adverse events to the appropriate authorities within the United States. Safety Data Exchange Agreement at 1, 3, Pl. Ex. 7; Bua Dep. 103:23-105:2, Pl. Ex. 1; *see* MacAllister Dep. 155:10-14; 163:5-9, Pl. Ex. 2. Besins S.A. has no role or responsibility for reporting adverse events or pharmacovigilance in the United States. Safety Data Exchange Agreement at 1, 3, Appx. 3, Pl. Ex. 7; Bua Dep. 104:19-22, Pl. Ex. 1. Besins S.A. merely forwarded any adverse event reports; AbbVie was responsible for assessing the adverse events and registering such information obtained within the United States with the FDA. Safety Data Exchange Agreement at 4-8, Pl. Ex. 7; *see* Bua Dep. 104:19-22, Pl. Ex. 1. Besins S.A.'s role in the United States is as a licensor of AndroGel to AbbVie. Bua Dep. 105:15-16, Pl. Ex. 1. In that role, Besins S.A. manufactured and distributed AndroGel, provided

safety data from non-United States sources, and collected royalties. *Id.* 104:4-18; 105:15-106:7. There is no evidence that Besins S.A. failed to pass along the relevant information to AbbVie. In fact, Plaintiffs' Opposition is completely devoid of any specific action attributable to Besins S.A. that can support Plaintiffs' claim for negligence.

In addition, Plaintiffs mischaracterize both Besins entities' relationship with AbbVie and AndroGel. While Besins S.A. has met with AbbVie on occasion, these meetings were "very sparse," Bua Dep. 29:16-18, Pl. Ex. 1, and it is undisputed that Besins S.A. had no responsibility for or control over AbbVie's marketing activities. There is no evidence that Besins "contributed" to the Advisory Committee briefing document. Opp'n at 8. The mere fact that Besins' corporate name was mentioned in the briefing document is insufficient to support a claim that there was any actionable conduct by Besins. Similarly, while Besins Inc. was responsible for the relationship with AbbVie in the United States regarding contract and patent issues, MacAllister Dep. 56:2-20, Pl. Ex. 2, it is undisputed that Besins Inc. had no involvement in the other aspects actually relevant to Plaintiffs' claims, such as marketing or distribution.

Plaintiffs' negligent design claim also fails because, as stated above, Plaintiffs have no evidence that there ***is*** a defect—only a conclusory and unsupported allegation. This is particularly fateful when paired with this Court's previous ruling that a negligent design defect claim cannot be maintained without Plaintiffs demonstrating the existence of a feasible alternative design. Plaintiffs have brought forth no evidence of such a design. *See* Mot. at 14.

Finally, Plaintiffs make the immaterial point that unjust enrichment claims may be independently actionable under individual states' laws. Opp'n at 10. Whether a separate cause of action or a derivative claim, an essential element of unjust enrichment is that a party has *unjustly* retained a benefit. *Blythe Holdings, Inc. v. DeAngelis*, 750 F.3d 653, 658 (7th Cir. 2014). While

Plaintiffs claim that Besins profited from AndroGel after deciding not to pursue additional safety studies despite being aware of insufficient testing, this ignores the reality that under its licensing agreement with AbbVie, Besins had no right to run studies of the product in the United States. MacAllister Dep. 163:5-9, Pl. Ex. 2. Besins licensed AndroGel to AbbVie while the product was still in formulation. *Id.* 163:13-14. In sum, no matter how Plaintiffs label their claims against Besins, they all fall short because they all rely on generalized and uncontroversial facts that fail to support their claims and fail to point to any specific action by Besins.

CONCLUSION

For the foregoing reasons, Defendants Besins Healthcare S.A. and Besins Healthcare Inc. respectfully request that the Court grant summary judgment dismissing all claims against both entities.

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Respectfully submitted,

By: */s/ Michelle Hart Yeary*

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CERTIFICATE OF SERVICE

I, Michelle Hart Yeary, hereby certify that on May 3, 2018, the foregoing document was filed via the Court's CM/ECF system, which will automatically serve and send email notification of such filing to all registered attorneys of record.

/s/ Michelle Hart Yeary